4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration-Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0498. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export of Food and Drug Administration-Regulated Products: Export Certificates

OMB Control Number 0910-0498--Extension

In April 1996, the FDA Export, Reform, and Enhancement Act of 1996 (FDAERA) (Pub. L. 104-134) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of sections 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications. In January 2011, section 801(e)(4)(A) was amended by the FDA Food Safety Modernization Act (Pub. L. 111-353) to provide authorization for export certification fees for food and animal feed.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated food, animal feed, pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act. FDA has developed various types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act. Four of those certificates are discussed in this notice: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. FDA has updated the certificates as part of the

proposed collection of information to account for the amendment authorizing export certification fees for food and animal feed. Table 1 lists the different certificates and details their uses:

Table 1.--Certificates and Uses

Type of Certificate	Use
"Supplementary Information Certificate to Foreign Government Requests" "Exporter's Certification Statement Certificate to Foreign Government" "Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)"	For the export of products legally marketed in the United States
"Supplementary Information Certificate of Exportability Requests" Exporter's Certification Statement Certificate of Exportability"	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act
"Supplementary Information Certificate of a Pharmaceutical Product" "Exporter's Certification Statement Certificate of a Pharmaceutical Product"	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license
"Supplementary Information Non-Clinical Research Use Only Certificate" "Exporter's Certification Statement (Non-Clinical Research Use Only)"	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to the appropriate offices.

In the *Federal Register* of November 27, 2017 (82 FR 56031), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. The burden hours have decreased from the previous approval.

Table 2.--Estimated Annual Reporting Burden[1]

FDA Center	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Center for Biologics Evaluation and Research	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research	3,680	1	3,680	1	3,680
Center for Veterinary Medicine	1,925	1	1,925	1	1,925
Total					30,606

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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